Atty. Docket No: 2877 (203-3419)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S):	Richard D. Gresham	EXAMINER:	Michael G. Mendoza
SERIAL NO.:	10/720,510	GROUP:	3734
FILED:	November 24, 2003	DATED:	December 17, 2009

TITLE: **SHEATH INTRODUCTION APPARATUS AND METHOD**

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BRIEF ON APPEAL

Sir:

This is an appeal from a Final Office Action dated June 25, 2009 ("Final Office Action") and the Advisory Action dated September 30, 2009 ("Advisory Action") in the above-identified application. This Brief is accompanied by the requisite fees set forth in 37 C.F.R. §41.20 (b)(2).

I. REAL PARTY IN INTEREST

The real party in interest for this application is Tyco Healthcare Group LP (d/b/a/ Covidien) having a principal office at 60 Middletown Avenue, North Haven, CT 06473.

II. RELATED APPEALS AND INTERFERENCES

Appellants' legal representative and/or the assignee of Appellants' interest in the above-identified application are not aware of any related appeals, interferences or judicial proceedings which may be related to, directly affect, or be directly affected by or have a bearing on any decision by the Board of Patent Appeals and Interferences in this appeal.

CERTIFICATE OF TRANSMISSION UNDER 37 C.F.R. §1.8(a)

I hereby certify that this correspondence is being transmitted on the date below with the United States Patent and Trademark Office, PO Box 1450, Alexandria, VA 22313-1450, via electronic submission.

Dated: **December 17, 2009**

Julie Yanopulos

III. STATUS OF CLAIMS

The instant application was originally filed with 28 Claims. Claims 29-31 were added by amendment. Claims 27-30 have been cancelled. Independent Claims 1 and 17 and dependent Claims 2-16, 18-26 and 31 are pending in this application and are involved in this Appeal. Each of these Claims stands finally rejected as set forth in the Final Office Action and the Advisory Action.

An accurate copy of Claims 1-26 and 31 is provided in the Claims Appendix.

IV. STATUS OF AMENDMENTS

The Advisory Action indicates that the response to the Final Office Action filed on August 25, 2009 (referred to on the Advisory Action under "Request for Reconsideration/Other") has been considered but failed to place the application in condition for allowance.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Claim 1 is directed to a sheath system for enabling access through an opening in the body of a patient. (Specification, Page 4, lines 5-6). The sheath system includes a dilation assembly having a radially expandable tubular sheath defining a lumen having a first cross-sectional area when in a non-expanded condition. (Specification, Page 4, lines 6-8). The sheath system further includes a handle assembly operatively coupled to a proximal end of the tubular sheath. (Specification, Page 4, lines 8-9). The handle assembly defines an aperture formed therein. (Specification, Page 4, line 9-10). A first thread is defined on the handle assembly in the

aperture thereof. (Specification, Page 4, lines 10-11). The sheath system also includes an expansion assembly including a tubular member defining a lumen having a second cross-sectional area which is larger than the first cross-sectional area of the tubular sheath of the dilation assembly. (Specification, Page 4, lines 11-13). The tubular member includes an outer surface defining a second thread. (Specification, Page 4, line 14). The second thread is formed along substantially an entire length of the tubular member from a location at least in close proximity to a distal end of the tubular member to a location in close proximity to a proximal end of the tubular member. (Specification, Page 15, line 1; FIG. 8). The second thread is arranged for engaging the first thread to axially advance the tubular member along the entire length thereof through the tubular sheath. (Specification, Page 15, lines 3-9).

Claim 17 is directed to a method of using a sheath system to enable access through an opening in the body of a patient. (Specification, Page 6, lines 1-2). The method includes the step of inserting a dilation assembly, having a radially expandable sheath defining a lumen and a proximal housing defining an aperture and a first thread in the aperture, into the opening in the body of the patient. (Specification, Page 6, lines 2-5). The method further includes the step of introducing an expansion assembly into the lumen of the dilation assembly to radially expand the lumen of dilation assembly and the opening in the body of the patient. (Specification, Page 6, lines 6-8). The expansion assembly has a tubular member with an outer surface defining a second thread. (Specification, Page 6, lines 6-7). The second thread is formed along substantially an entire length of the tubular member from a location at least in close proximity to a distal end of the tubular member to a location in close proximity to a proximal end of the tubular member. (Specification, Page 15, line 1; FIG. 8). The introduction of the expansion

assembly includes engaging the first thread with the second thread to axially advance the tubular member along the entire length thereof through the tubular sheath. (Specification, Page 6, lines 8-9).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The following issues are on appeal:

A) whether Claims 1-3, 7-9, 11, 12, 17-20, 23-25 and 31 are rendered obvious under 35 U.S.C. § 103(a) in view of U.S. Patent No. 5,827,227 to Delago et al. ("Delago") in view of U.S. Patent No 5,911,714 to Wenstrom, Jr. ("Wenstrom");

B) whether Claims 1-9, 11, 12, 14 and 15-26 are rendered obvious under 35 U.S.C. § 103(a) over U.S. Patent No. 6,080,174 to Dubrul et al ("Dubrul") in view of Delago in further view of Wenstrom;

C) whether Claim 10 is rendered obvious under 35 U.S.C. § 103(a) over Delago/Wenstrom or the combination of Dubrul/Delago/Wenstrom; and

D) whether Claim 13 is rendered obvious under 35 U.S.C. § 103(a) over Dubrul/Delago/Wenstrom as applied to claims 1-9, 11, 12, 14 and 15-26 above, and further in view of U.S. Patent No. 6,676,355 to Frova et al. ("Frova").

VII. ARGUMENT

A. Claims 1-3, 7-9, 11, 12, 17-20, 23-25 and 31 are patentable under 35 U.S.C. § 103(a) over Delago in view of Wenstrom

Claims 1-3, 7-9, 11, 12, 17-20, 23-25 and 31 stand rejected under 35 U.S.C. § 103(a) as being obvious over Delago in view of Wenstrom. Appellant respectfully submits that this rejection should be reversed.

1. Claims 1-3, 7-9, 11, 12 and 31

Independent Claim 1 recites a sheath system for enabling access through an opening in the body of a patient. The sheath system includes a dilation assembly having a radially expandable tubular sheath defining a lumen having a first cross-sectional area when in a non-expanded condition and a handle assembly operatively coupled to a proximal end of the tubular sheath. The handle assembly defines an aperture formed therein. A first thread is defined on the handle assembly in the aperture thereof. The sheath system further includes an expansion assembly including a tubular member defining a lumen having a second cross-sectional area which is larger than the first cross-sectional area of the tubular sheath of the dilation assembly. The tubular member has an outer surface defining a second thread formed along substantially an entire length of the tubular member from a location at least in close proximity to a distal end of the tubular member to a location in close proximity to a proximal end of the tubular member. The second thread is arranged for engaging the first thread to axially advance the tubular member along the entire length thereof through the tubular sheath.

Contrary to the allegations made by the Examiner, Delago in view of Wenstrom does not render obvious Claim 1 because Delago, taken alone or in any proper combination with Wenstrom, fails to disclose, teach or suggest all of the limitations recited in Claim 1. More particularly, Delago in view of Wenstrom fails to disclose, teach or suggest a sheath system including, *inter alia*, an expansion assembly including a tubular member, the tubular member having an outer surface defining a second thread formed along substantially an entire length of the tubular member from a location at least in close proximity to a distal end of the tubular member to a location in close proximity to a proximal end of the tubular member, the second thread being arranged for engaging the first thread to axially advance the tubular member along the entire length thereof through the tubular sheath, as recited in Claim 1.

With reference to FIG. 1 of Delago, reproduced herein below, Delago discloses a catheter apparatus 10 including a guide wire 11, a dilator 12 and a sheath 13. Dilator 12 is a substantially tubular member having a housing 14 for securely engaging dilator 12 with a housing 16 mounted on a proximal end of sheath 13. Threads 50 are formed on housing 14 for engaging threads 51 formed in cap 86 of housing 16. Threads 50 are not formed on any portion of the tubular member of dilator 12, and therefore, do not extend along any length thereof, much less substantially along an entire length thereof.

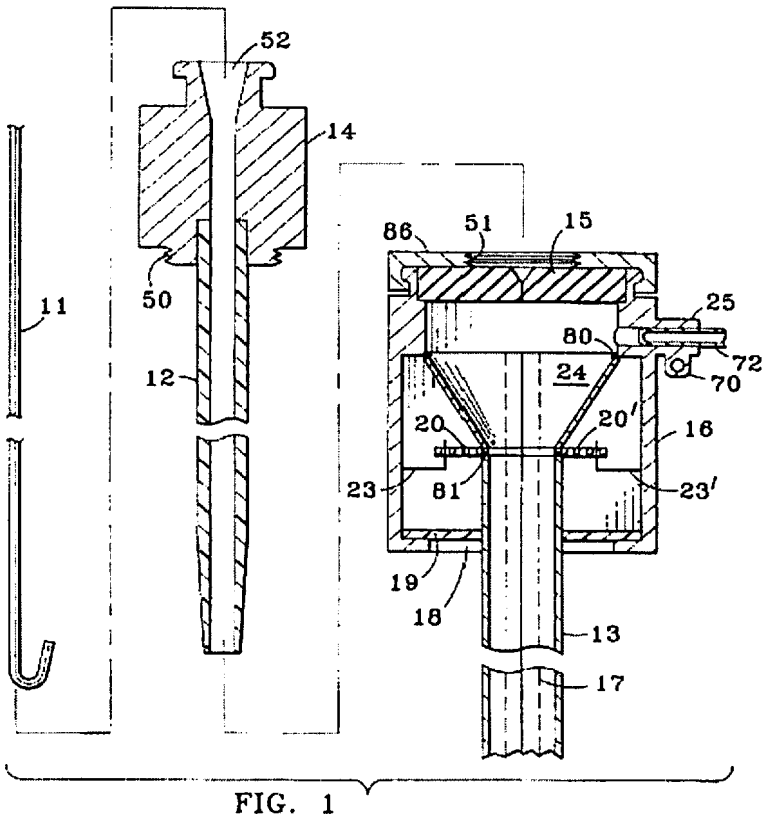


FIG. 1

The Examiner relies on Wenstrom to disclose a thread formed along substantially an entire length of the tubular member. With reference to FIGS. 31 and 32 of Wenstrom, reproduced hereinbelow, Wenstrom discloses a cannula housing 200 including a helical thread 225 formed on the outer surface of distal portion 205. However, helical thread 225 is configured to directly engage tissue 500 such that twisting of cannula housing 200 causes thread 225 to set securely into tissue 500. Helical thread 225 is not configured to engage a dilation assembly, much less to engage a first thread of a tubular sheath to axial advance the tubular member along the entire length thereof through the tubular sheath, as recited in claim 1.

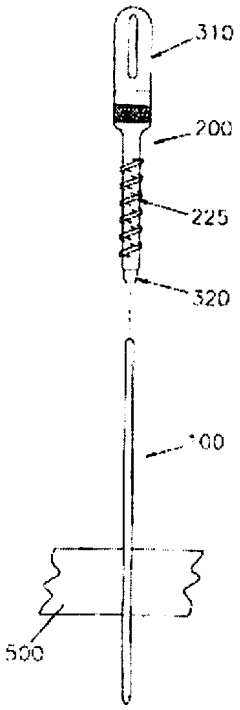


FIG. 30

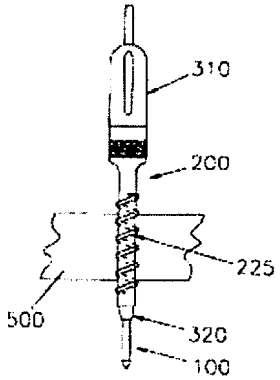


FIG. 31

Contrary to the Examiner's assertion, it would not have been obvious to combine a helical thread configured for penetrating tissue with the tubular member of a dilator configured to expand a tubular sheath. Additionally, although, as noted by the Examiner, the threaded portion of Delago advances the expansion assembly forward through the tubular sheath, the threaded portion of Delago is formed on the housing and not the tubular member. Thus, the threaded portion of Delago is configured to secure the housing of the dilator with the housing of the expansion assembly, and is not configured to secure the tubular member with the tubular sheath, as the Examiner proposes. Further, the threaded portion does not axially advance the tubular member "along the entire length thereof through the tubular sheath".

Thus, Delago in view of Wenstrom fails to render obvious Claim 1 and Appellants submit that Claim 1 is in condition for allowance. For at least these same reasons, *inter alia*, Appellant submits that Claims 2, 3, 7-9, 11, 12 and 31, which depend from Claim 1, are also in condition for allowance. Therefore, Appellant submits that the rejection of Claims 1-3, 7-9, 11, 12 and 31 under 35 U.S.C. § 103(a) should be reversed.

2. Claims 17-20 and 23-25

Independent Claim 17 recites a method of using a sheath system to enable access through an opening in the body of a patient. The method includes the steps of inserting a dilation assembly, having a radially expandable sheath defining a lumen and a proximal housing defining an aperture and a first thread in the aperture, into the opening in the body of the patient. The method further includes the step of introducing an expansion assembly, having a tubular member with an outer surface defining a second thread, into the lumen of the dilation assembly to radially expand the lumen of dilation assembly and the opening in the body of the patient. The second thread being formed along substantially an entire length of the tubular member from a location at least in close proximity to a distal end of the tubular member to a location in close proximity to a proximal end of the tubular member. The introduction of the expansion assembly includes engaging the first thread with the second thread to axially advance the tubular member along the entire length thereof through the tubular sheath.

Contrary to the allegations made by the Examiner, Delago in view of Wenstrom does not render obvious Claim 17 because Delago, taken alone or in any proper combination with Wenstrom, fails to disclose, teach or suggest all of the limitations recited in Claim 17. More

particularly, Delago in view of Wenstrom fails to disclose, teach or suggest a method of using a sheath system including, *inter alia*, the steps of introducing an expansion assembly, having a tubular member with an outer surface defining a second thread formed along substantially an entire length of the tubular member from a location at least in close proximity to a distal end of the tubular member to a location in close proximity to a proximal end of the tubular member, into the lumen of the dilation assembly to radially expand the lumen of dilation assembly and the opening in the body of the patient, the introduction including engaging the first thread with the second thread to axially advance the tubular member along the entire length thereof through the tubular sheath, as recited in Claim 17.

As discussed above, Delago discloses a catheter apparatus 10 including a guide wire 11, a dilator 12 and a sheath 13. Dilator 12 is a substantially tubular member having a housing 14 for securely engaging dilator 12 with a housing 16 mounted on a proximal end of sheath 13. Threads 50 are formed on housing 14 for engaging threads 51 formed in cap 86 of housing 16. Threads 50 are not formed on any portion of the tubular member of dilator 12, and therefore, do not extend along any length thereof, much less substantially along an entire length thereof. Wenstrom discloses a cannula housing 200 including a helical thread 225 formed on the outer surface of distal portion 205. Helical thread 225 is configured to directly engage tissue 500 such that twisting of cannula housing 200 causes thread 225 to set securely into tissue 500. Helical thread 225 is not configured to engage a dilation assembly, much less to engage a first thread of a tubular sheath to axial advance the tubular member along the entire length thereof through the tubular sheath.

Contrary to the Examiner's assertion, it would not have been obvious to combine a helical thread configured for penetrating tissue with the tubular member of a dilator configured to expand a tubular sheath. Additionally, although, as noted by the Examiner, the threaded portion of Delago advances the expansion assembly forward through the tubular sheath, the threaded portion of Delago is formed on the housing and not the tubular member. Thus, the threaded portion of Delago is configured to secure the housing of the dilator with the housing of the expansion assembly, and not to secure the tubular member with the tubular sheath, as the Examiner proposes. Further, the threaded portion does not axially advance the tubular "along the entire length thereof through the tubular sheath".

Thus, Delago in view of Wenstrom fails to render obvious Claim 17 and Appellants submit that Claim 17 is in condition for allowance. For at least these same reasons, *inter alia*, Appellant submits that Claims 18-20 and 23-25, which depend from Claim 17, are also in condition for allowance. Therefore, Appellant submits that the rejection of Claims 17-20 and 23-25 under 35 U.S.C. § 103(a) should be reversed.

B. Claims 1-9, 11, 12, 14 and 15-26 are patentable under 35 U.S.C. § 103(a) over Dubrul in view of Delago in further view of Wenstrom

Claims 1-9, 11, 12, 14 and 15-26 stand rejected under 35 U.S.C. § 103(a) over U.S. Patent No. 6,080,174 to Dubrul et al ("Dubrul") in view of Delago in further view of Wenstrom. Appellants respectfully submit that these rejections should be reversed.

1. Claims 1-9, 11, 12 and 14-16

Independent Claim 1 recites a sheath system for enabling access through an opening in the body of a patient. The sheath system includes a dilation assembly having a radially expandable tubular sheath defining a lumen having a first cross-sectional area when in a non-expanded condition and a handle assembly operatively coupled to a proximal end of the tubular sheath. The handle assembly defines an aperture formed therein. A first thread is defined on the handle assembly in the aperture thereof. The sheath system further includes an expansion assembly including a tubular member defining a lumen having a second cross-sectional area which is larger than the first cross-sectional area of the tubular sheath of the dilation assembly. The tubular member has an outer surface defining a second thread formed along substantially an entire length of the tubular member from a location at least in close proximity to a distal end of the tubular member to a location in close proximity to a proximal end of the tubular member. The second thread is arranged for engaging the first thread to axially advance the tubular member along the entire length thereof through the tubular sheath.

Contrary to the allegations made by the Examiner, Dubrul in view of Delago in further view of Wenstrom does not render obvious Claim 1 because Dubrul, taken alone or in any proper combination with Delago and/or Wenstrom, fails to disclose, teach or suggest all of the limitations recited in Claim 1. More particularly, Delago in view of Wenstrom fails to disclose, teach or suggest a sheath system including, *inter alia*, an expansion assembly including a tubular member, the tubular member having an outer surface defining a second thread formed along substantially an entire length of the tubular member from a location at least in close proximity to

a distal end of the tubular member to a location in close proximity to a proximal end of the tubular member, the second thread being arranged for engaging the first thread to axially advance the tubular member along the entire length thereof through the tubular sheath, as recited in Claim 1.

According to the Examiner, Dubrul teaches a sheath system substantially as claimed, including a dilation assembly and an expansion assembly. However, as the Examiner duly notes, Dubrul fails to teach that the dilation and expansion assemblies include first and second threads, respectively, and Dubrul and Delago fail to teach that the second thread is formed along substantially an entire length of the tubular member. As such, the Examiner relies on Delago to teach the use of common first and second threads for attaching components in a sheath system, and on Wenstrom to teach the second thread formed along substantially an entire length of the tubular member.

As discussed above, Delago fails to teach or disclose the thread being formed along a substantial portion of the tubular member. Instead, with reference back to FIG. 1 of Delago, reproduced hereinabove, thread 50 of dilator assembly 12 is formed on housing 14, not on the tubular member, and only extends a portion of a length of housing 14. Thus, Dubrul, taken alone or in any proper combination with Delago, fails to suggest or disclose a dilator assembly including a tubular member, "the tubular member having an outer surface defining a second thread formed along substantially an entire length of the tubular member from a location at least in close proximity to a distal end of the tubular member to a location in close proximity to a proximal end of the tubular member, the second thread being arranged for engaging the first

thread to axially advance the tubular member along the entire length thereof through the tubular sheath," as recited in Claim 1.

Thus, Dubrul in view of Delago and further in view of Wenstrom fails to render obvious Claim 1 and Appellant submits that Claim 1 is in condition for allowance. For at least these same reasons, *inter alia*, Appellant submits that Claims 2, 3, 7-9, 11, 12 and 31, which depend from Claim 1, are also in condition for allowance. Therefore, Appellant submits that the rejection of Claims 1-3, 7-9, 11, 12 and 31 under 35 U.S.C. § 103(a) should be reversed.

2. Claims 17-26

Claim 17 recites a method of using a sheath system including, *inter alia*, the steps of introducing an expansion assembly, having a tubular member with an outer surface defining a second thread formed along substantially an entire length of the tubular member from a location at least in close proximity to a distal end of the tubular member to a location in close proximity to a proximal end of the tubular member, into the lumen of the dilation assembly to radially expand the lumen of dilation assembly and the opening in the body of the patient, the introduction including engaging the first thread with the second thread to axially advance the tubular member along the entire length thereof through the tubular sheath.

Contrary to the allegations made by the Examiner, Dubrul in view of Delago in further view of Wenstrom does not render obvious Claim 1 because Dubrul, taken alone or in any proper combination with Delago and/or Wenstrom, fails to disclose, teach or suggest all of the limitations recited in Claim 1. More particularly, Delago in view of Wenstrom fails to disclose, teach or suggest a method of using a sheath system including, *inter alia*, the steps of introducing

an expansion assembly, having a tubular member with an outer surface defining a second thread formed along substantially an entire length of the tubular member from a location at least in close proximity to a distal end of the tubular member to a location in close proximity to a proximal end of the tubular member, into the lumen of the dilation assembly to radially expand the lumen of dilation assembly and the opening in the body of the patient, the introduction including engaging the first thread with the second thread to axially advance the tubular member along the entire length thereof through the tubular sheath, as recited in Claim 17.

As discussed above, according to the Examiner, Dubrul teaches a method of using a sheath system substantially as claimed, including a dilation assembly and an expansion assembly. However, as the Examiner duly notes, Dubrul fails to teach that the dilation and expansion assemblies include first and second threads, respectively, and Dubrul and Delago fail to teach that the second thread is formed along substantially an entire length of the tubular member. As such, the Examiner relies on Delago to teach the use of common first and second threads for attaching components in a sheath system, and on Wenstrom to teach the second thread formed along substantially an entire length of the tubular member.

Thus, Delago in view of Wenstrom fails to render obvious Claim 17 and Appellants submit that Claim 17 is in condition for allowance. For at least these same reasons, *inter alia*, Appellant submits that Claims 18-26, which depend from Claim 17, are also in condition for allowance. Therefore, Appellant submits that the rejection of Claims 17-26 under 35 U.S.C. § 103(a) should be reversed.

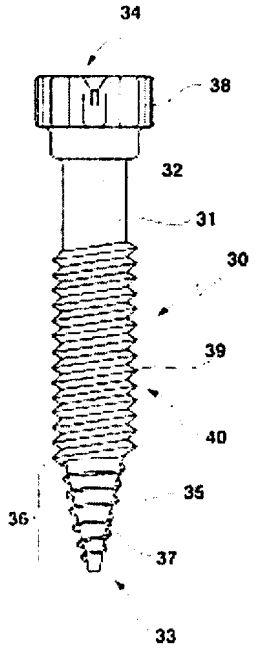
C. Claim 10 is patentable under 35 U.S.C. § 103(a) over Delago/Wenstrom or the combination of Dubrul/ Delago/Wenstrom

As discussed above, niether Delago, Dubrul, nor Wenstrom, taken alone or in any proper combination suggest or disclose all the features of independent Claim 1. Since Claim 10 depends from Claim 1, Appellant submits that the rejection of Claim 10 under 35 U.S.C. § 103(a) should be reversed.

D. Claim 13 is patentable under 35 U.S.C. § 103(a) over Dubrul/Delago/Wenstrom further in view of Frova

With reference to FIG. 3 of Frova, reproduced below, Frova discloses a tracheostomy dilator for widening a tracheal opening. The tracheostomy dilator includes threads on an outer surface that are configured to engage tissue. There is no suggestion, motivation or teaching to use the tracheostomy dilator for any purpose other than to widen an opening in the trachea to access the airway of a patient. A person of ordinary skill in the art of surgical instrument introduction systems, for accessing an abdominal cavity, would not look to a device for accessing an airway of a patient. Furthermore, as disclosed in column 4 lines 27-31 of Frova, first thread 35 is formed such that it has automatic cutting properties. This is necessary for the engagement of tissue wherein the tip creates an opening in the tissue. Incorporation of a dilator including a cutting thread formed along any portion thereof would result in the dilator cutting or shredding the tubular sheath upon insertion of the dilator assembly, thereby rendering the system inoperable.

Fig. 3



Therefore, the combination of Frova with Dubrul/Delago/Wenstrom is improper. Further, as discussed above, none of Delago, Dubrul, nor Wenstrom, taken alone or in any proper combination suggest or disclose all the features of independent Claim 1. Frova does not provide any disclosure that, when taken in any proper combination with Delago, Dubrul, and/or Wenstrom, cures the deficiencies of Delago, Dubrul and/or Wenstrom with regards to Claims 1. Since Claim 13 depends from independent Claim 1, Appellant submits that the rejection of Claim 10 under 35 U.S.C. § 103(a) should be reversed.

E. Conclusion

In view of the foregoing analysis and remarks, it is clear that the sheath system recited in independent Claim 1 and the method of using a sheath system recited in independent Claim 17, are not rendered obvious, by Delago in view of Wenstrom or Dubrul in view of Delago in further view of Wenstrom.

For at least the foregoing reasons, it is respectfully submitted that:

Claims 1-3, 7-9, 11, 12, 17-20, 23-25 and 31 are not render obvious under 35 U.S.C. § 103(a) over Dubrul in view of Wenstrom, and this rejection should be reversed;

Claims 1-9, 11, 12, 14 and 15-26 are not rendered obvious under 35 U.S.C. § 103(a) over Dubrul in view of Delago in further view of Wenstrom, and this rejection should be reversed;

Claim 10 is not rendered obvious under 35 U.S.C. § 103(a) over Delago/Wenstrom or the combination of Dubrul/Delago/Wenstrom; and

Claim 13 is not rendered obvious under 35 U.S.C. § 103(a) over Dubrul/ Delago/Wenstrom further in view of Frova.

Please charge any deficiency as well as any other fee(s) which may become due under 37 C.F.R. §1.16 and/or 1.17 at any time during the pendency of this application, or credit any overpayment of such fee(s) to Deposit Account No. 21-0550. Also, in the event any extensions of time for responding are required for the pending application(s), please treat this paper as a petition to extend the time as required and charge Deposit Account No. 21-0550 therefore.

An early and favorable response on the merits is earnestly requested.

Respectfully submitted,

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VIII. CLAIMS APPENDIX

1. (Rejected) A sheath system for enabling access through an opening in the body of a patient, the sheath system comprising:

a dilation assembly having a radially expandable tubular sheath defining a lumen having a first cross-sectional area when in a non-expanded condition, and a handle assembly operatively coupled to a proximal end of the tubular sheath, the handle assembly defining an aperture formed therein, and a first thread defined on the handle assembly in the aperture thereof; and

an expansion assembly including a tubular member defining a lumen having a second cross-sectional area which is larger than the first cross-sectional area of the tubular sheath of the dilation assembly, the tubular member having an outer surface defining a second thread formed along substantially an entire length of the tubular member from a location at least in close proximity to a distal end of the tubular member to a location in close proximity to a proximal end of the tubular member, the second thread being arranged for engaging the first thread to axially advance the tubular member along the entire length thereof through the tubular sheath.

2. (Rejected) The sheath system according to claim 1, further comprising an introducer sized for receipt in the lumen of the radially expandable sheath, when the radially expandable sheath is in the non-expanded condition.

3. (Rejected) The sheath system according to claim 1, wherein the tubular member of the expansion assembly is configured and dimensioned to be removably received within the aperture formed in the handle assembly of the dilation assembly.

4. (Rejected) The sheath system according to claim 2, wherein the tubular sheath of the dilation assembly comprises a mesh of individual filaments.

5. (Rejected) The sheath system according to claim 4, wherein the filaments are elastic so that radial expansion of the tubular sheath causes axial shortening of the tubular sheath.

6. (Rejected) The sheath system according to claim 2, wherein the tubular sheath comprises a tubular braid of individual filaments.

7. (Rejected) The sheath system according to claim 2, wherein a shaft of the introducer is removably receivable within the lumen of the tubular sheath.

8. (Rejected) The sheath system according to claim 3, wherein distal advancement of the tubular member of the expansion assembly results in radial expansion of the tubular sheath from the first cross-sectional area to the second cross-sectional area.

9. (Rejected) The sheath system according to claim 8, further comprising a seal at the proximal end of the expansion assembly.

10. (Rejected) The sheath system according to claim 9, wherein the seal is made from at least one of an elastomeric polymeric material and polyisoprene.

11. (Rejected) The sheath system according to claim 8, further comprising a dilator configured and dimensioned to be removably received within the lumen of the tubular member of the expansion assembly.

12. (Rejected) The sheath system according to claim 11, wherein a distal end of the dilator is tapered.

13. (Rejected) The sheath system according to claim 12, wherein the distal end of the dilator defines threads.

14. (Rejected) The sheath system according to claim 12, wherein the dilator has a length such that when the dilator is received within the lumen of the tubular member, the tapered distal end thereof extends beyond a distal end of the tubular member.

15. (Rejected) The sheath system according to claim 14, further including an introducer having a shaft, wherein the shaft of the introducer has a length such that when the introducer is received within the lumen of the tubular sheath, a distal end thereof extends beyond a distal end of the tubular sheath.

16. (Rejected) The sheath system according to claim 9, further comprising a converter configured and dimensioned to be removably attached to a proximal end of the expansion assembly, the converter including an aperture formed therein, the aperture of the converter having a cross-sectional area less than a cross-sectional area of the opening formed in the seal of the expansion assembly.

17. (Rejected) A method of using a sheath system to enable access through an opening in the body of a patient, comprising:

inserting a dilation assembly, having a radially expandable sheath defining a lumen and a proximal housing defining an aperture and a first thread in the aperture, into the opening in the body of the patient; and

introducing an expansion assembly, having a tubular member with an outer surface defining a second thread formed along substantially an entire length of the tubular member from a location at least in close proximity to a distal end of the tubular member to a location in close proximity to a proximal end of the tubular member, into the lumen of the dilation assembly to radially expand the lumen of dilation assembly and the opening in the body of the patient, the introduction including engaging the first thread with the second thread to axially advance the tubular member along the entire length thereof through the tubular sheath.

18. (Rejected) The method according to claim 17, further comprising inserting an introducer into the dilation assembly prior to the step of inserting the dilation assembly.

19. (Rejected) The method according to claim 17, further comprising inserting a dilator into the expansion assembly prior to the step of introducing the expansion assembly.

20. (Rejected) The method according to claim 17, wherein the lumen of the dilation assembly has a first cross-sectional area and the lumen of the expansion assembly has a second cross-sectional area which is larger that the first cross-sectional area of the lumen of the dilation assembly.

21. (Rejected) The method according to claim 20, wherein the sheath is made from a mesh of individual filaments.

22. (Rejected) The method according to claim 21, wherein radial expansion of the tubular sheath causes axial shortening of the sheath.

23. (Rejected) The method according to claim 17, wherein the introduction of the expansion assembly includes distal advancement of the tubular member of the expansion assembly through the sheath of the dilation assembly, resulting in radial expansion of the sheath.

24. (Rejected) The method according to claim 17, wherein engaging the first thread with the second thread includes rotation of the tubular member with respect to the dilation assembly.

25. (Rejected) The method according to claim 17, wherein the expansion assembly includes a seal disposed across the lumen of the tubular member, the seal including an opening formed therein, and the method further includes introducing an instrument into the tubular member through the opening of the seal.

26. (Rejected) The method according to claim 25, further including removably attaching a converter to a proximal end of the tubular member, wherein an opening formed in the converter has a cross-sectional area which is less than the cross-sectional area of the opening formed within the seal.

Claims 27-30. (Canceled)

31. (Rejected) The sheath system of claim 1, wherein the second thread extends along the entire length of the tubular sheath when the tubular member is fully inserted into the tubular sheath.

IX. EVIDENCE APPENDIX

None

X. RELATED PROCEEDINGS APPENDIX

None